PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/674,914
Filing Date:	September 30, 2003
Applicant:	Bevil J. Hogg
Group Art Unit:	3736
Examiner:	Huong Q. Nguyen
Title:	Method and Apparatus for Improved Surgical Navigation Employing Electronic Identification with Automatically Actuated Flexible Medical Devices
Attorney Docket:	5236-000452

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL APPEAL BRIEF /
RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Sir:

In response to the Examiner's Notification of Non-Compliant Appeal Brief mailed on April 13, 2009, Appellant respectfully submits this Supplemental Appeal Brief to provide a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by paragraph and to the drawings, if any, by reference characters. The Appellants submit that the Appeal Brief fee was previously paid on September 22, 2008, but hereby authorizes the Commissioner to charge, if necessary, any fees required under 37 C.F.R. §1.17(f) to deposit account 08-0750.

APPELLANT'S BRIEF ON APPEAL

Pursuant to 37 C.F.R. § 41.37, Appellants submit their Brief on Appeal, as follows:

REAL PARTY IN INTEREST – UNDER 37 C.F.R. § 41.37(c)(1)(i)

The real party in interest in this appeal is Stereotaxis, Inc., a Delaware corporation, having a place of business at 4320 Forest Park Avenue, Suite 100, St. Louis, MO 63108, by virtue of an assignment recorded at Reel 014802, Frame 0204.

RELATED APPEALS & INTERFERENCES - UNDER 37 C.F.R. § 41.37(c)(1)(ii)

To the best of Appellants' knowledge, no other appeals or interferences are pending which will directly affect, be directly affected by or have a bearing on the Board's decision in the present pending appeal.

STATUS OF THE CLAIMS – UNDER 37 C.F.R. § 41.37(c)(1)(iii)

On June 26, 2008, Appellants appealed from the rejection in the Final Office Action mailed March 27, 2008. The Finality of the March 27, 2008 Office Action was withdrawn in a subsequent December 10, 2008 Office Action that is responsive to the claims filed January 9, 2008. Accordingly, claims 1-6, 8-17, 38-40 and 51-52 are pending and being appealed, and claims 7, 18-37, 41-50 and 53 have been cancelled.

- A copy of the claims presently being appealed (Claims 1-6, 8-17, 38-40 and 51-52) is provided in the attached Claims Appendix.
- A copy of the December 10, 2008 Office Action placing claims 1-6, 8-17, 38-40 and 51-52 in the application under rejection is provided in the attached Evidence appendix.

STATUS OF AMENDMENTS – UNDER 37 C.F.R. § 41.37(c)(1)(iv)

A Final Office Action was mailed March 27, 2008, in response to which an Amendment after Final was mailed May 13, 2008. Subsequently, an Advisory Action was mailed December 15, 2008, which denied entry of the Amendment After Final, such that the pending claims under appeal are the claims filed on January 9, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER – UNDER 37 C.F.R. § 41.37(c)(1)(v)

Independent Claim 1

A medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end portion one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, and an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification;

a navigation device configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation;

an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and spacing therebetween, that were obtained from the electronic identification device.

With regard to the elongate medical device recited in independent claim 1, the present Application discloses an elongate medical device 51 (see Fig.1 and ¶ [0020]). With regard to the one or more magnetically responsive elements in independent claim

1, the application discloses a medical device having on its distal end portion one or more magnetically responsive elements 101 (Fig. 2 and ¶ [0022]). With regard to the electronic identification device in independent claim 1, the application discloses an electronic identification device 121 (Figs. 2, 3A), also referenced as a device identification pod (see ¶ [0022]).

With regard to the navigation device in independent claim 1, the application discloses a navigation device configured to create a magnetic field (see actuation system 54 in Fig. 1 and ¶ [0020]). With regard to the claimed navigation determining actuation control variables, the application states: "The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031])

With regard to the electronic interface in independent claim 1, the application discloses an electronic interface (see actuation controller 60 in Fig. 1 and ¶ [0020]). With regard to the processor and at least one software program, the application states that the "interface includes at least two computer programs that run on the processor." (see ¶ [0021], [0029]). With regard to the interface providing actuation instructions, the application discloses in ¶ [0020] a: "workstation computer 64 that is connected to a graphical user interface 67 and other input devices such as a mouse 69, a keyboard 70, a pen tablet 71, a device advancer 72 and/or a joystick 73," and states in ¶ [0031] that:

"user inputs are accepted through any of the user input devices that may be the mouse 69, keyboard 70, pen tablet 71, device advancer 72 or joystick 73. These inputs generally dictate a choice of target location (parameterized by a set of variables {y}) that it is desired to access or a path or trajectory (parameterized by a set of variables {z}) that is desired for the device tip to follow. The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs."

With regard to the feature of instructions taking into account the physical and geometric properties, the present application states in ¶ [0031] that:

"The device identification stored in pod 121 discloses a set {p} of physical and geometrical properties (specified under certain standard conditions) relevant to the automatically actuated flexible device to the workstation computer 64. As stated earlier, this characterization may include one or more of several quantities such as lengths of device segments, elastic properties of the device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing."

Thus, the present application discloses an elongate medical device in ¶ [0022], which states that "the medical device 51 generally comprises a flexible and usually hollow shaft 97 (see Fig. 2), a magnetically responsive element 101 (see Fig.2) and "A device identification pod 121 incorporating stored electronic identification information is affixed to the device." The "device identification stored in pod 121 discloses a set {p} of physical and geometrical properties...[which] include one or more of several quantities such as length of device segments, elastic property of device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing." (see ¶ [0030])

The Application discloses "a navigational control system 57" (see Fig. 1) which is a "magnet system that creates a magnetic field that can be used to steer the device 51...[where] a magnetically responsive element on the distal end of the medical device responds to the external magnetic field to change the direction of the distal end of the device" (see ¶ [0020]). With regard to the set of physical and geometrical properties, the Application states that "information is processed by the workstation computer 64 to derive a set of variables," where "The navigation control algorithm determines a set of

actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031])

The Application discloses an electronic interface in the form of a "workstation computer 64 that is connected to a graphical user interface 67" (see Fig. 1) where in one implementation the "interface includes at least two computer programs that run on the processor." (see ¶ [0021], [0029]) As noted above, information is processed by workstation computer 64 to derive a set of variables characterizing device configuration, where a "navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target."(¶ [0031]).

Independent Claim 38

A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties including one or more cross-sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device, where the one or more cross-sectional areas of the device, and the elastic property of the device are used in navigational control algorithms for guiding the device;

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

With regard to the elongate flexible medical device in independent claim 38, the present application states in ¶ [0022] that "in a preferred implementation the elongate flexible medical device 51 (see Fig. 1) generally comprises a flexible and usually hollow shaft 97 (see Fig. 2)."

With regard to the memory device in independent claim 38, the present application states that "A device identification pod 121 (see Figs. 2,3A) incorporating stored electronic identification information is affixed to the device at the proximal end." With regard to the memory device of independent claim 38, provided on the flexible medical device, the Application discloses memory chip 131 (see Fig. 3B and ¶ [0024]) "for storage of device information and device physical and geometrical properties". Exemplary memory chips cited include " an EPROM or other non-volatile memory storage chip for storage of device identification and device physical and geometrical properties". With regard to the memory including cross-sectional areas and elastic properties of the device, the present application states in ¶ [0031] that:

"The device identification stored in pod 121 discloses a set {p} of physical and geometrical properties (specified under certain standard conditions) relevant to the automatically actuated flexible device to the workstation computer 64. As stated earlier, this characterization may include one or more of several quantities such as lengths of device segments, elastic properties of the device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing."

With regard to the control system in independent claim 38, the Application discloses "an actuation system 54 that is controlled by a navigational control system 57" (See ¶ [0020]). Control system 57 generally comprises an actuation controller 60 (see

Fig. 1) in communication with an actuation system 54 (see Fig. 1). ¶ [0020] discloses "the navigation control system could operate conventional pull wires built into the elongate medical device, or it could hydraulically operate chambers built into the medical device, or operate magnetostrictive or electrostrictive elements built into the elongate medical device. The elongate medical device 51 could employ any navigational method for selectively changing the orientation of the distal end of the device."

With regard to an interface for accepting inputs from the user of independent claim 38 to cause the control system to selectively change the position and/or orientation of the elongate medical device, the Application discloses in Fig. 1 and ¶ [0021] "an actuation controller 60 with a graphical user interface 62 and a set of input devices 63, and a workstation computer 64 that is connected to a graphical user interface 67 and other input devices such as a mouse 69, a keyboard 70, a pen tablet 71, a device advancer 72 and/or a joystick 73. The navigational control system may also be a "magnet system that creates a magnetic field that can be used to steer the device 51." (see ¶ [0020])

With regard to the set of physical and geometrical properties, the Application states that "Some or all of this information is processed by the workstation computer 64 to derive a set of variables," where "The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031])

The Application discloses a "workstation computer 64 that is connected to a graphical user interface 67" (see ¶ [0021]) The Application discloses "user inputs are accepted through any of the user input devices that may be the mouse 69, keyboard 70,

pen tablet 71, device advancer 72 or joystick 73...[which] inputs generally dictate a choice of target location." (see ¶ [0031]) As noted above, information is processed by workstation computer 64 to derive a set of variables characterizing the device configuration, where a "navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target." (see ¶ [0031]).

Independent Claim 52

A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device including at least one magnet;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device; wherein the control system is a magnetic navigation system for controlling the elongate medical device that further includes at least one magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type; and

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information including the magnet dimension or magnet type obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

With regard to the elongate flexible medical device element of independent claim 52, including at least one magnet, the present application discloses a magnetically responsive element 101 (see Fig. 2 and ¶ [0022])) in medical device 51 (see Fig. 1) that "generally comprises a flexible and usually hollow shaft 97 (See Fig. 2). The magnetically responsive element "imparts device actuation in the distal portion 104 (see Fig. 2 and ¶ [00322]) of the shaft.

With regard to the memory device element of independent claim 52 provided on the flexible medical device, the Application discloses memory chip 131 (see Fig. 3B and ¶ [0024]) "for storage of device identification and device physical and geometrical properties ".Exemplary memory chips cited include " an EPROM or other non-volatile memory storage chip for storage of device identification and device physical and geometrical properties".

With regard to a control system of independent claim 52 for controlling the position and/or orientation of the distal end of the elongate medical device, the Application discloses "an actuation system 54 that is controlled by a navigational control system 57" (See ¶ [0020]). Control system 57 generally comprises an actuation controller 60 (see Fig. 1) in communication with an actuation system 54 (see Fig. 1), where "in a preferred embodiment, the actuation system 54 is a magnet system that creates a magnetic field that can be used to steer the device 51 within an operating volume 58 within a subject's body" (see Fig. 1 and ¶ [0020]).

With regard to the interface of independent claim 52, the application discloses an interface 57 for accepting inputs from the user of independent claim 38 to cause the control system to selectively change the position and/or orientation of the elongate medical device, the Application discloses in Fig. 1 and ¶ [0021] "an actuation controller

60 with a graphical user interface 62 and a set of input devices 63, and a workstation computer 64 that is connected to a graphical user interface 67 and other input devices such as a mouse 69, a keyboard 70, a pen tablet 71, a device advancer 72 and/or a joystick 73. The navigational control system may also be a "magnet system that creates a magnetic field that can be used to steer the device 51." (see ¶ [0020])

With regard to independent claim 52, the present application states in ¶ [0022] that "the medical device 51 (see Fig. 1) generally comprises a flexible and usually hollow shaft 97 (see Fig. 2), a magnetically responsive element 101 (see Fig. 2) that imparts device actuation in the distal portion" and "A device identification pod 121 (see Figs. 2, 3A) incorporating stored electronic identification information is affixed to the device."

The Application discloses "a navigational control system 57" which is a "magnet system that creates a magnetic field that can be used to steer the device 51...[where] a magnetically responsive element on the distal end of the medical device responds to the external magnetic field to change the direction of the distal end." (see ¶ [0020])

The "device identification stored in pod 121 discloses a set {p} of physical and geometrical properties...[which] include one or more of several quantities such as length of device segments, elastic properties of device segments, stiffness, device cross sectional details, magnet dimensions, magnet type and other magnet characteristics, the number of magnets and their spacing." (see ¶ [0030])

The Application discloses a "workstation computer 64 that is connected to a graphical user interface 67" (see ¶ [0021]) The Application discloses "user inputs are accepted through any of the user input devices that may be the mouse 69, keyboard 70,

pen tablet 71, device advancer 72 or joystick 73...[which] inputs generally dictate a choice of target location." (see ¶ [0031])

With regard to the set of physical and geometrical properties, the Application states that "Some or all of this information is processed by the workstation computer 64 to derive a set of variables," where "The navigation control algorithm determines a set of actuation control variables {u} which when applied drive the device towards the user-specified target criteria, given all the available inputs." (see ¶ [0031])

GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL – UNDER 37 C.F.R. § 41.37(c)(1)(vi)

Appellants present the following issues for review:

1. Is the invention set forth in Claims 1-6, 8-9, 11-17 and 52 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551).
2. Is the invention set forth in Claim 10 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551) and in further view of *Burnside* (U.S. Pat. No. 6,237,604).
3. Is the invention set forth in Claims 38-40 non-obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Garibaldi* (U.S. Pat. No. 6,401,723) and in further view of *Osadchy* (U.S. Pat. No. 6,266,551).

ARGUMENT – UNDER 37 C.F.R. § 41.37(c)(1)(vii)

1. 1st GROUND OF REJECTION ON APPEAL

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 1st ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

Independent Claim 1

Claim 1 is not obvious over *Stereotaxis* in view of *Osadchy* for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed of A Device With Information On The Number of Magnetic Elements For Use In Determining Navigation Variables

The December 10, 2008 Office Action states on page 5 that *Osadchy* discloses a device with electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy

and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions that take into account information on the number of magnetically responsive elements and spacing therebetween.

As the Supreme Court said, there must be an apparent reason to combine known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween that are used in determining navigational control variables for orienting/guiding the distal end of the medical device.

Thus, the Appellants submit that claim 1 is not obvious in view of *Stereotaxis* or *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result of *Osadchy's* Catheter With A Calibration Offset, And Would Not Have Been Productive of Appellant's Device With Information On The Number of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings might have recognized that the *Stereotaxis* system could be improved by including *Osadchy's* stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellants, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellants. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellants' invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellants' device that stores the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device.

The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration distance between a sensing coil and tip would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellants submit that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 1 having stored information including a number of magnetically responsive elements.

Independent Claim 52

Claim 52 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed of A Device With Information On The Number of Magnetic Elements For Use In Determining Navigation Variables

The December 10, 2008 Office Action states on page 9 that *Osadchy* discloses a device with electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c

11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information on the number of magnetically responsive elements and spacing therebetween. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Appellants submit that claim 52 is not obvious in view of *Stereotaxis* or *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result of *Osadchy's* Catheter With A Calibration Offset, And Would Not Have Been Productive of Appellants' Device With Information On The Number of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings may have recognized that the *Stereotaxis* system could be improved by including a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellants, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellants. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellants' invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellants' device that stores the number of magnetically responsive elements and spacing

therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and tip would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined Osadchy's teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellants submit that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 52 having stored information including a number of magnetic elements.

Claims 2-6, 8-9 and 11-17

With regard to claims 2-6, 8-9 and 11-17, these claims ultimately depend from claim 1, which Appellants believe to be allowable in view of the above remarks. As such, the Appellants submit that claims 2-6, 8-9 and 11-17 are also allowable for at least these reasons.

2. *2nd GROUND OF REJECTION ON APPEAL*

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 2nd ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

Claim 10

With regard to claim 10, this claim depends from claim 1, which Appellants believe to be allowable in view of the above remarks. As such, the Appellants submit that claim 10 is also allowable for at least these reasons.

3. *3rd GROUND OF REJECTION ON APPEAL*

Pursuant to 37 C.F.R. § 41.37(c)(1)(vii), the following provides the contentions of appellants with respect to the 3rd ground of rejection above presented for review in accordance with 37 C.F.R. § 41.37(c)(1)(vi).

Independent Claim 38

The Appellants submit that claim 38 is not obvious over the above cited references for the following reasons:

I. Garibaldi is 102(e) prior art that is not available as a reference under 35 USC 103(c);

II. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the cross-sectional area and elastic properties of the device for use in determining navigation variables, and

III. The combination of references would not be productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Garibaldi,* Since *Garibaldi* Is Not Available As A Reference

The present application has an effective filing date of September 20, 2002 (the filing date of provisional application 60/414,574), and the Garibaldi patent has an issue date of June 11, 2002. Thus, the Appellants submit that while the *Garibaldi* reference may be §102(e) prior art, it does not qualify for purposes of obviousness under 35 U.S.C. § 103(a) since the present application and the *Garibaldi* patent were subject to an obligation of assignment to the same entity under 35 USC §103(c)(1).

Regarding commonly assigned patents and applications, 35 USC §103(c)(1) states that:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The Applicants submit that the *Garibaldi* patent is owned by Stereotaxis, Inc., by virtue of an assignment recorded at Reel 010877, Frame 0432. The Applicants submit that the present application is owned by Stereotaxis, Inc., by virtue of an assignment recorded at Reel 014802, Frame 0204. Accordingly, the Applicants submit that the *Garibaldi* patent and the present application are both co-owned by Stereotaxis. The Applicants also submit that at the time of the present invention, the inventors Jeffrey Garibaldi, Raju Viswanathan and Bevil J. Hogg were subject to an obligation of assignment to Stereotaxis, Inc. Thus, the Applicants submit that the *Garibaldi* patent is

disqualified as a reference for purposes of obviousness under 35 U.S.C. § 103(c).

As the Viswanathan ('173) application is not an appropriate reference for establishing an obviousness rejection in view of the above, the Applicants submit that claim 38 cannot be obvious based on any teachings in the *Garibaldi* patent, and the *Garibaldi* patent cannot be considered in combination with the *Stereotaxis* and *Osadchy* references.

II. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed of A Device With Information on Elasticity/Cross-sectional Area For Use in Determining Navigation Variables

The December 10, 2008 Office Action states on page 11 that *Osadchy* discloses a device with electronic information on physical properties of the device that includes geometric properties including the position of the tip 26 relative to coils 60, 62, 64, where the information is used to determine calibration correction data to enable proper determination of tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (Osadchy, c. 10, ll. 55; c. 15, ll. 6-7).

Osadchy's distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (Osadchy, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information including the cross-sectional area and elastic properties of the device. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the references in a manner that would result in the fashion claimed by the patent application. KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (U.S., 2007).

The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Appellants submit that claim 38 is not obvious in view of *Osadchy's* teachings.

III. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result of *Osadchy's* Catheter With A Calibration Offset, And Would Not Have Been Productive of Appellants' Device With Information On Cross-sectional Area Of The Device For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings may have recognized that the *Stereotaxis* system could be improved by including a stored

calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellants, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellants. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Appellants' invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Appellants' device that stores the cross-sectional area and elastic properties of the device, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and tip would be obvious, since it

does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined Osadchy's teachings of an offset in a manner that would have predictably resulted in including the cross-sectional area and elastic properties of the device, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Appellants submit that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 38 having stored information including a cross-sectional area and elastic properties of the device.

Claims 39-40

With regard to claims 39-40, these claims ultimately depend from claim 38, which Appellants believe to be allowable in view of the above remarks. As such, the Appellants submit that claims 39-40 are also allowable for at least these reasons.

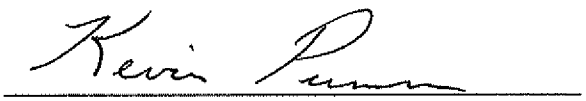
Claim 51

With regard to claim 51, the December 10, 2008 Office Action states on page 3 that it is believed that claim 51 was meant to be cancelled and will be treated as such in the rejection. Accordingly, Appellants have treated claim 51 as though it is cancelled, for purposes of Appeal.

CONCLUSION

Appellants respectfully submit that the Examiner has not shown that claims 1-6, 8-9, 11-17 and 52 are obvious under 35 U.S.C. § 103(a) over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551). The Examiner also has not shown that claim 10 is obvious over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551) and *Burnside* (U.S. Pat. No. 6,237,604), or that claims 38-40 are obvious under 35 U.S.C. § 103(a), over *Stereotaxis* (WO 00/07641) in view of *Garibaldi* (U.S. Pat. No. 6,401,723) and *Osadchy* (U.S. Pat. No. 6,266,551). Accordingly, reversal of the rejections of claims 1-6, 8-9, 10-17, 38-40, 52 are respectfully requested.

Respectfully submitted,



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Date: May 12, 2009

CLAIMS APPENDIX
UNDER 37 C.F.R. § 41.37(c)(1)(viii)

1. (Previously Presented) A medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device having on its distal end portion one or more magnetically responsive elements that respond to an externally applied magnetic field to change the direction of the distal end of the medical device, and an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification;

a navigation device configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation;

an electronic interface for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor and at least one software program that enables navigation control only in the presence of the electronic identification device, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device, which instructions take into account the physical and geometric properties of the elongate medical device, including the number of magnetically responsive elements and spacing therebetween, that were obtained from the electronic identification device.

2. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes a memory, and wherein the interface includes a reader for reading the memory.

3. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes a memory unit and a processing unit that communicates with the interface for transferring information.

4. (Original) The medical navigation system according to claim 2 wherein the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate.

5. (Original) The medical navigation system according to claim 3 wherein the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate.

6. (Original) The medical navigation system according to claim 1 wherein the electronic identification device is a circuit that is connected to the interface.

7. (Cancelled)

8. (Original) The medical navigation system according to claim 2 wherein the memory contains unique identifying information about the device, and wherein the interface includes a database of the unique identifying information for devices with which the interface is intended to operate.

9. (Original) The medical navigation system according to claim 3 wherein the memory contains unique identifying information about the device, and wherein the interface includes a database of the unique identifying information for devices with which the interface is intended to operate.

10. (Original) The medical navigation system according to claim 1 wherein the electronic identification device is a RF circuit that transmits a signal to the interface.

11. (Original) The medical navigation system according to claim 1 wherein the interface includes a plurality of programs, each adapted for use with a different type of elongate flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present.

12. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes an integrated circuit.

13. (Original) The medical navigation system according to claim 1 wherein the interface operates on the electronic identification device to prevent reuse of the elongate flexible medical device.

14. (Original) The medical navigation system according to claim 1 wherein the interface tracks elapsed time of use of the identified elongate flexible medical device and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit.

15. (Original) The electronic identification device according to claim 3 wherein the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device.

16. (Original) The medical navigation system according to claim 1 wherein the electronic identification device includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device.

17. (Original) The medical navigation system according to Claim 1 wherein the at least one software program controls navigation by employing a computational model of flexible device physics.

18. – 37. (Cancelled)

38. (Previously Presented) A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties including one or more cross-sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device, where the one or more cross-sectional areas of the device,

and the elastic property of the device are used in navigational control algorithms for guiding the device;

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information, including the one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

39. (Original) The medical navigation system according to claim 38 wherein the interface incorporates a software program that controls navigation by employing a computational model of flexible device physics.

40. (Original) The system according to claim 38 wherein the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database.

41. – 50. (Cancelled)

51. (Previously Presented) The medical navigational control system according to claim 50 wherein the information including physical and geometric properties of the device includes at least one of the length of one or more flexible segments of the device, one or more cross-sectional areas of the device, and an elastic property of the device.

52. (Previously Presented) A medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device including at least one magnet;

a memory device provided on the flexible medical device that includes information on the physical and geometric properties of the elongate medical device that are relevant to navigational control of the device;

a control system for controlling the position and/or orientation of the distal end of the elongate medical device; wherein the control system is a magnetic navigation system for controlling an elongate medical device that further includes at least one magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type; and

an interface for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device; the interface sending actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information including the magnet dimension or magnet type obtained from the memory device, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device.

53. (Cancelled)

EVIDENCE APPENDIX UNDER 37 C.F.R. § 41.37(c)(1)(iX)

- A copy of the Office Action mailed December 10, 2008 placing the present application under final rejection is provided.

RELATED PROCEEDINGS APPENDIX - UNDER 37 C.F.R. § 41.37(c)(1)(x)

NONE.

60532937.1

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,914	09/30/2003	Bevil J. Hogg	5236-000452	8982

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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,914	HOGG ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-6,8-17,38-40,51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17,38-40,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Appeal Brief filed 9/22/2008. In light of Applicant's arguments, the finality of the previous Office Action is withdrawn and replaced with the following. As the amendments to the claims and drawing have not been entered as indicated in the attached Advisory Action, the Office action is responsive to claims filed 1/9/2008. **Claims 1-6, 8-17, 38-40, and 51-52** remain pending and under prosecution.

Drawings

2. The drawings remain objected to as failing to comply with 37 CFR 1.84(p)(5) because Applicant has failed to address that they do not include the following reference sign(s) mentioned in the description: "57" in ¶0019 and "97" in ¶0021 of p.7 of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claims 51-52** remain objected to because Applicant has failed to address the following informalities: Claim 51 recites dependency upon cancelled claim 50. It is therefore believed that Claim 51 meant to be cancelled as well and will be treated as such in the following rejection. Applicant is requested to review said claim and determine its appropriate status and/or dependency. Claim 52 should recite "a control system…for controlling THE elongate medical device that further includes at least one magnet." It is noted that the recitation of the magnet is already previously introduced in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claim 1-6, 8-9, 11-17, and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis (WO 00/07641) in view of Osadchy et al (US Pat No. 6266551).

6. In regards to **Claim 1**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate flexible medical device in a subject's body, the system comprising:

an elongate flexible medical device 24 having on its distal end 76 one or more magnetically responsive elements 78 that respond to an externally applied magnetic field to

change the direction of the distal end of the medical device, best seen in Figure 1-3 (p.3: 17-20; p.8: 33-37; p.9: 4-11);

a navigation device 22 configured to create a magnetic field used to steer the elongate flexible medical device, and to determine, as a function of the physical and geometric properties (p.5: 1-5; p.8: 37-39; p.9: 1-17) actuation control variables for an applied actuation consisting essentially of an external magnetic field, where the navigation device determines and applies an appropriate magnetic field direction for actuating the distal end of an elongate flexible medical device and thereby changing its orientation (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29);

an electronic interface 36, 38, 40 for selectively operating the navigation device for selectively controlling the orientation of the distal end of the elongate flexible medical device, the electronic interface comprising a processor in computer 26 and including at least one software program, wherein the interface provides actuation instructions to the navigation device for controlling the distal end of the device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26), which instructions take into account the physical and geometric properties of the elongate medical device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

7. However, Stereotaxis does not disclose an electronic identification device on the elongate medical device that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and identification information that provides for elongate flexible medical device identification, wherein navigation of the device is only enabled in the presence of the electronic identification device.

8. Osadchy et al disclose a catheter system comprising an electronic identification device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and spacing therebetween, i.e. d_y and d_2 (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36 of the actual position and orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the electronic identification device 90 (Col.16: 26-43). Osadchy et al also disclose an electronic interface 36 comprising a processor 40 and includes at least one software program that enables use and thus navigation control of the elongate medical device only in the presence of the electronic identification device (Col.5: 60-62; Col.17: 33-46).

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include an electronic identification device on the elongate medical device that includes information about the elongate medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, and the instructions to the navigation device take into account the number of magnetically responsive elements and spacing therebetween obtained from the electronic identification device, and wherein navigation of the device is only enabled in the presence of the electronic identification device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the elongate

medical device for proper navigation by taking into account the positioning of the magnetically responsive elements, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

10. In regards to **Claims 2**, Osadchy et al disclose the electronic identification device 90 includes a memory (Col.16: 37-43), and wherein the interface 36 includes a reader for reading the memory (Col.16: 52-55).

11. In regards to **Claims 3**, Osadchy et al disclose the electronic identification device 90 includes a memory unit (Col.16: 37-43) and a processing unit that communicates with the interface for transferring information (Col.7: 62-67).

12. In regard to **Claims 4-5 and 8-9**, Osadchy et al disclose the memory contains unique identifying information about the type of device, and wherein the interface includes a database of the unique identifying information of the type of devices with which the interface is intended to operate (Col.17: 33-46).

13. In regards to **Claim 6**, Osadchy et al disclose the electronic identification device 90 is a circuit, i.e. microcircuit best seen in Figure 5 that is connected to the interface 36.

14. In regards to **Claim 11**, Stereotaxis in combination with Osadchy et al disclose the interface includes a plurality of programs, each adapted for use with a different type of elongate

flexible medical device, each program operating only when an electronic identification device for the particular type of elongate flexible medical device is present (Osadchy et al Col.5: 50-62).

15. In regards to **Claim 12**, Osadchy et al disclose the electronic identification device 90 includes an integrated circuit.

16. In regards to **Claim 13**, Osadchy et al disclose the interface 36 operates on the electronic identification device 90 to prevent reuse of the elongate flexible medical device (Col.18: 46-55).

17. In regards to **Claim 14**, Osadchy et al disclose the interface 36 tracks elapsed time of use of the identified elongate flexible medical device 20 and invalidates use of the identified elongate flexible medical device when the elapsed time exceeds a pre-defined limit (Col.17: 55-65; Col.18: 46-55).

18. In regards to **Claim 15**, Osadchy et al disclose the processing unit operates on the memory unit to prevent reuse of the elongate flexible medical device (Col.18: 9-55).

19. In regards to **Claim 16**, Osadchy et al disclose the electronic identification device 90 includes memory, and wherein the interface adds to or deletes information stored on the memory to prevent reuse of the device (Col.18: 9-55).

20. In regards to **Claim 17**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

21. In regards to **Claim 52**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24 including at least one magnet 78, best seen in Figure 1-3;

a control system 22 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29); wherein the control system is a magnetic navigation system for controlling the elongate medical device that includes at least one magnet and uses information on the physical and geometric properties of the elongate medical device for navigational control of the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5: 6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p. 7: 15-26; p.8: 37-39; p.9: 1-17).

22. However, Stereotaxis does not disclose a memory device provided on the flexible medical device that includes stored information on the physical and geometric properties of the elongate medical device such as at least a magnet dimension or a magnet type that are relevant to

navigational control of the device. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements 60, 62, 64 and magnet dimension or spacing therebetween, i.e. d_y and d_2 (Col.11: 1-22, 26-31, 65-67; Col.12: 1-16), best seen in Figure 1-2, wherein the number of magnetically responsive elements and the spacing therebetween are used to determine calibration correction data (Col.15: 17-21, 53-58) to enable proper determination by computer 36 of the actual position and orientation of the distal tip 26 of the elongate medical device in the body (Col.15: 26-29, 64-67; Col.16: 1-13, 52-55) and wherein said unique calibration correction data for said elongate medical device is stored on the memory device 90 (Col.16: 26-43).

23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis to include a memory device on the flexible medical device that includes information about the medical device such as the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and magnet dimension, and the instructions to the control system are dependent in part upon the number of magnetically responsive elements and magnet dimension obtained from the memory device, as taught by Osadchy et al, to enable accurate determination of the position and orientation of the flexible medical device for proper navigation by taking into account the positioning of the magnets and thus their dimensions, and to ensure that such pertinent identifying information is provided for each particular elongate medical device before use for improved navigation and safety.

24. **Claim 10** is rejected under 35 U.S.C. 103(a) as being obvious over Stereotaxis in view of Osadchy et al, further in view of Burnside et al (US Pat No. 6237604).

25. Stereotaxis in combination with Osadchy et al in the manner above disclose the electronic identification device above that transmits a signal to the interface above but do not disclose said device is RF circuit. Burnside et al teach the use of an RF circuit to effectively transmit a signal (abst). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the circuit of Stereotaxis as modified by Osadchy et al a RF circuit as taught by Burn as an effective means for such.

26. **Claims 38-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stereotaxis in view of Garibaldi et al (US Pat No. 6401723), further in view of Osadchy et al.

27. In regards to **Claim 38**, Stereotaxis discloses a medical navigation system for controlling the distal end of an elongate medical device in the body of the patient comprising:

an elongate flexible medical device 24, best seen in Figure 1;

a control system 22, 26 for controlling the position and/or orientation of the distal end 76 of the elongate medical device (p.5: 6-17, 31-38; p.6: 23-27; p.7: 6-26; p.8: 7-29), where the elastic property of the device are used in navigational control algorithms for guiding the device, i.e. the stiffness or elasticity of the device must be taken into account when determining the magnetic field intensity required to control the distal end of the device (p.7: 15-26; p.8: 37-39; p.9: 1-17);

an interface 36, 38, 40 for accepting inputs from the user to cause the control system to selectively change the position and/or orientation of the elongate medical device (p.4: 26-30; p.5:

6-10; p.6: 1-15, 24-40; p.7: 1-26); the interface sending instructions to the control system dependent in part upon the medical device's physical and geometric property information, including one or more cross-sectional areas of the device, and the elastic property of the device obtained from the memory device as explained above, wherein the physical and geometric properties of the device are used in navigational control algorithms for guiding the device (p.5: 1-5; p.8: 37-39; p.9: 1-17).

28. However, Stereotaxis does not disclose one or more cross sectional areas of the elongate device used in navigational control algorithms for guiding the device. Garibaldi et al teach that the cross sectional area of the coil wire of an analogous elongate medical device is directly proportional to the magnetic moment of the coil, which is then directly proportional to the magnetic torque applied to the distal end of the elongate medical device (Col.4: 36-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis such that one or more cross sectional areas of the elongate device are used in navigational control algorithms for guiding the device as taught by Garibaldi et al to effectively take into account the effect of the cross sectional area on the magnetic torque of the elongate medical device.

29. However, Stereotaxis and Garibaldi et al do not disclose a memory device provided on the flexible medical device that includes the information on the physical and geometric properties including one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above. Osadchy et al disclose a catheter system comprising a memory device 90 on an elongate flexible medical device 20 that includes information on the physical and geometric

properties of the medical device, i.e. the position and orientation of distal tip 26 relative to coils 60, 62, 64 as well as information regarding the position of said coils or the gains of the coils (Col.2: 1-45, 65-66; Col.3: 1-4; Col.7: 21-29), to provide effective proper medical device identification before use (Col.17: 34-46).

30. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stereotaxis as modified by Garibaldi et al to include a memory device provided on the flexible medical device that includes the information on the physical and geometric properties such as one or more cross sectional areas of the elongate device and an elastic property of the elongate medical device that are relevant to navigational control of the device as described above, as taught by Osadchy et al, to ensure that such pertinent identifying information is provided for each particular flexible medical device before use for improved navigation and safety.

31. In regards to **Claim 39**, Stereotaxis discloses the at least one software program controls navigation by employing a computational model of flexible device physics.

32. In regards to **Claim 40**, Stereotaxis in combination with Osadchy et al disclose the memory device includes storing unique device identification information for the elongate flexible medical device, and wherein the interface includes a database of unique device identification information and corresponding device properties, and wherein the instructions sent to the control system take into account the device properties determined from the database (Osadchy et al Col.17: 33-46).

Response to Arguments

33. Applicant's arguments filed 8/26/2008 have been fully considered but they are not persuasive. In regards to Claims 1 and 52, Applicant contends that there is no motivation to combine Osadchy et al with Stereotaxis. However, it is noted that Osadchy et al teach that determination of the actual correct position of tip is done inside the body, from which the elongate medical device is subsequently navigated to its desired location (Col.15: 64-67). Please also see other citations of Osadchy et al above. Although Applicant contends that the combination of Stereotaxis and Osadchy et al would not produce Applicant's invention, it is respectfully submitted that from said teachings of Osadchy et al, one of ordinary skill in the art would recognize the need to determine the actual position of the tip for proper navigation of the elongate medical device. It is common sense to one of ordinary skill in the art that navigation requires precise knowledge of the start point as well as the end point of any device. From there, one of ordinary skill in the art would thus be reasonably led to include such determination into the navigation device of Stereotaxis and subsequently provide actuation instructions taking into account the actually position of the tip, which is determined by the number of magnetically responsive elements and spacing therebetween and a magnet dimension as elaborated above, for reasons such as taking into account the differences in actual tip position influenced by the number of the magnetically responsive elements, spacing therebetween, and dimension. Furthermore, it is noted that Osadchy et al teach calibration data may be stored in the elongate medical device necessary as necessary for the steering of the device (Col.19: 47-50). Thus, it is believed that Osadchy et al are not only aware of the need of using various physical and

geometric properties of the elongate medical device as essential in navigating the device, but also teach the advantages of such from specific properties such as the number of the magnetically responsive elements, spacing therebetween, and dimension.

34. Applicant's arguments with respect to claims 38-40 have been considered but are moot in view of the new ground(s) of rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736